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External Article Review

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External article review of: Efficacy of clozapine versus second-generation antipsychotics in people with treatment-resistant schizophrenia: a systematic review and individual patient data meta-analysis

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Review

The following is an External Article Review of a paper published in the April 2025 issue of Lancet Psychiatry*, found* here: https://www.thelancet.com/journals/lanpsy/article/PIIS2215-0366(25)00001-X/fulltext

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An individual patient data (IPD) meta-analysis that came out in Lancet Psychiatry in February compares clozapine with "second-generation antipsychotics" in people with treatment-resistant schizophrenia.[1]

All psychiatric textbooks I have read talk about first-, second-, and even third-generation drugs.[2,3] Some neuroleptics are called atypicals and some are called modern, suggesting you are outlandish if you prefer older drugs. As the drugs within these arbitrary classes are widely different in their effects, it is meaningless to divide them this way. It is industry jargon aimed at selling new drugs.

That the authors seem to be too beholden to the industry is also apparent from the declared conflicts of interest, e.g. for the corresponding author, psychiatrist Stefan Leucht.

The article starts this way (references omitted):

"Introduction. In up to a third of individuals with an acute episode of schizophrenia, standard antipsychotic treatment does not lead to sufficient improvement of symptoms. Clinical guidelines recommend the use of the antipsychotic clozapine in such cases, because it is considered more efficacious than other antipsychotics, especially in people with treatment-resistant schizophrenia (typically defined as insufficient response to two trials of different antipsychotics with adequate dose

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and duration)."

There are six obvious problems with this.

First, it is highly misleading to say that up to a third of patients do not have sufficient improvement of their symptoms. Virtually all patients do not have sufficient improvement since, according to Leucht himself, neuroleptics don't work. The least clinically relevant effect corresponds to about 15 points on the PANSS scale[4] commonly used in the trials. Yet, what was reported in the placebo-controlled trials of recent drugs submitted to the FDA was only 6 points, or 3% of the maximum score of 210 on this scale.[5]

Second, it is impossible for a clinician to decide if a particular drug has had an effect in a particular patient. No matter what the clinician thinks, it is extremely likely that there was no effect. The problem with clinical experience is that some patients will improve without any treatment, which clinicians erroneously interpret as an improvement caused by the drug.[2,3]

Third, when the drugs are to blame, it is insulting to put the blame on the patients by calling them "treatment-resistant."

Fourth, a popular saying is that madness is doing the same thing again and again expecting a different result. Psychiatrists excel in this futile discipline, but it won't help trying another antipsychotic as none of them work.[3]

Fifth, it won't help increasing the dose, as adding drugs or increasing the dose do not result in better outcomes.[6]

Sixth, an ineffective drug doesn't become effective if you take it for a long time.

In the Introduction, the authors write that clozapine should be used with caution because it has multiple harms - euphemistically called side-effects - which include weight gain, sedation, anticholinergic effects, and sialorrhea (which few people will know means excessive drooling). They also mention that clozapine can cause serious disorders, e.g. agranulocytosis (occurring in between 0.1% and 1% of the patients), myocarditis (between 0.01% and 0.1% of the patients), and seizures (between 1% and 10% of the patients).

How do you use a drug "with caution" that might kill you? It cannot be done, as deaths often come unexpectedly, e.g. because of cardiac arrest.[2,3] Clozapine is more harmful than other neuroleptics, but all the drugs are highly lethal. They kill 2 of 100 demented people in just 10 weeks.[7] We don't know how lethal they are in people with schizophrenia because virtually all patients were already in treatment with a neuroleptic before they got randomised, and those who are switched to placebo are exposed to withdrawal effects, which increase mortality.[8,9]

It cannot be doubted that neuroleptics play a major role for the very short life expectancy patients with schizophrenia have.[2,3] The conclusion of the new meta-analysis should therefore have been: Don't use clozapine for any of your patients with schizophrenia. But this is not how psychiatry is.[2,3,9]

What did the authors find and what is their message?

The authors included 12 trials (1052 patients) and found a nonsignificant difference of -0.6 on the PANSS scale (95% credible interval -4.0 to 2.6) between clozapine and other neuroleptics. This is 0.7% of the median PANSS score at baseline of 91.5, corresponding to a standardised mean difference of -0.03.

The authors dismiss their own, very clear finding in several remarkable ways and give the reader the impression that clozapine, after all, is better than other drugs.

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Under Results, they downgrade the confidence in the estimate of the primary outcome, the PANSS score, to very low. They say that "The unavailability of IPD for some studies and the potential risk of small trial or publication bias, the frequent and partly differential premature study discontinuation of participants, and the fact that four trials included patients intolerant of previous antipsychotics" led them to this conclusion.

These arguments are not valid. Researchers or companies that are unwilling to share their data often have something to hide; the authors tested for publication bias and did not find it (P = 0.66); premature discontinuation is common in trials of schizophrenia and would not be expected to favour one drug over another when similar drugs are being compared; and intolerance to antipsychotics is very common, as these drugs are very harmful and unpleasant to take, so this should not be a reason to downgrade the findings either.

In the Discussion section, the authors present additional arguments for downgrading their findings to virtually nothing. They say that the uncertainty in the results arises from the fact that symptoms of schizophrenia fluctuate, which leads to uncertainty in imputation, and that their "adjustment for differences in duration of illness, baseline severity, and sex only incompletely explained the variance in results. These limitations, although partly mitigated by the use of IPD, led to a GRADE assessment of very low quality of evidence."

None of these arguments make much sense and they should not have led to a downgrading of the findings. Moreover, it is wrong to use baseline severity as a predictor in a regression analysis. If you regress change in symptoms on initial symptom severity, this corresponds to looking at $(x - y) = ax + b$, where x is the initial value and y the final value. Since x appears on both sides of the equation, 50% of the variation is already explained. This means that even when two factors are unrelated, the analysis will show a relation, which is spurious. The authors write that "higher baseline symptom severity were associated with larger improvement in overall symptoms after 6-8 weeks." This is nothing but a mathematical artefact.

The authors present a post-hoc analysis in the Results section of 7 trials (547 patients) for which they did not have individual patient data. In this analysis, clozapine was significantly better than other neuroleptics, standardised mean difference 0.24 (0.04 to 0.43).

Even though their own meta-analysis is by far the most reliable one ever performed of clozapine, the authors draw on unreliable meta-analyses in their Discussion section. They mention a meta-analysis in patients who were not treatment resistant and note that clozapine was the "top-ranked drug based on efficacy, superior to all other second-generation antipsychotics, albeit based on a small sample size (n=270)."

Whether patients are treatment resistant or not, is immaterial, as all patients can be said to be treatment resistant for drugs that don't work. More importantly, meta-analyses of published trial reports are notoriously unreliable in psychiatry. Half of all deaths and half of all suicides are missing,[10] and comparisons of published reports with internal company reports have shown how unreliable publications are.[2,3,9,11]

But the authors did not downgrade such unreliable evidence.

The grotesqueness of all this was once revealed in a paper title: "Why olanzapine beats risperidone, risperidone beats quetiapine, and quetiapine beats olanzapine: an exploratory analysis of head-to-head comparison studies of second-generation antipsychotics."[12] In a mathematical sense, this is impossible. If A is higher than B, and B is higher than C, then C cannot be higher than A, but psychiatry often makes the impossible possible.

The authors pull another rabbit out of the pharmacological hat, observational

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studies. They say that a meta-analysis of observational studies showed that "clozapine use was associated with lower risk of hospitalisation and all-cause discontinuation." They admit that there could be systematic differences between patients receiving clozapine or other drugs that prevent causal conclusions, but then why mention such studies at all?

Astonishingly, the authors write that "uncertainty remains regarding superiority of clozapine." Based on their meta-analysis, we can be certain that clozapine is not better than other drugs.

The authors' conclusion is even more odd. They say that, "In case of disabling symptoms despite adequate treatment with other second-generation antipsychotics, clozapine might then be considered, since other evidence suggests an advantage with clozapine."

I wonder why they did the most reliable meta-analysis ever and then so readily dismissed it, based on unreliable evidence? Was it to protect guild interests and financial interests in relation to the drug industry? What else could it be?

The authors also use psychiatry's eternal mantra, which is to rely on clinical experience even though it is useless when drugs have little or no effect: "However, clinicians and patients should bear in mind that the superiority of clozapine in treatment-resistant schizophrenia is not certain, and therefore the outcome on clozapine should be critically evaluated (preferably using a validated brief rating scale)."

Finally, they suggest carrying out "an adequately powered controlled trial in individuals with strictly defined treatment-resistant schizophrenia." As I have already noted, madness is to never stop doing the same thing, expecting a different outcome.

The abstract

The abstract of a scientific paper is of utmost importance as few people read beyond it. This is where the authors explain what they did, what they found, and how they interpret it, in a very condensed way.

The authors write: "The confidence in the evidence was graded as very low." If our confidence in the best evidence we have - an individual patient data meta-analysis of the randomised trials - is so low, we might as well ignore all drug trials in psychiatry. Perhaps we should, but that is another discussion. I have called for introducing a new paradigm for testing psychiatric drugs.[13]

The authors seem to be influenced by Cochrane methods and the meaningless jargon that is now obligatory for people writing Cochrane reviews.[14] The abstract concludes that, "This IPD meta-analysis found a small and uncertain advantage of other second-generation antipsychotics."

As the difference was not statistically significant and very close to zero, then why write that there was a small advantage when there wasn't?

When my co-author and I in 2023 onwards tried to update our Cochrane review of mammography screening,[14] we faced a road-block. One of the things the Cochrane editors demanded, with reference to the Cochrane Handbook,[15] was that our statement "did not show a benefit in terms of a reduction in breast cancer mortality" should be "may show little or no difference in terms of a reduction in breast cancer mortality." We objected, as there was no statistically significant reduction in breast cancer mortality and as it is subjective whether a difference is small or not. We were ignored, and our update, with more deaths, was rejected in February 2025 for no good reason. I had anticipated this because I had been exposed to Cochrane censorship and editorial misconduct many times earlier.[16] I had therefore published our updated mortality results in 2023, on my website.[17]

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The last sentence in the abstract is: "Given the side-effects of clozapine, the observed uncertainty regarding clozapine's superiority warrants prudent use and further research."

As I have argued, one cannot use lethal drugs prudently, and there is no need for more research, but for more honesty when psychiatrists publish unwelcome research.

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Author Rejoinder

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Submitted 3/14/2025

We appreciate the opportunity to respond to the comments regarding our publication.

While we acknowledge the critique provided by Prof. Gøtzsche, we believe that some aspects of his argumentation deviate from the central issue of our research. Contrary to the widely held belief in the field, our position challenges the assumption that clozapine is unequivocally superior in efficacy. We continue to assert that a well-designed, industry-independent randomized controlled trial (RCT) comparing clozapine with other second-generation antipsychotics is necessary (as detailed in our original article). Furthermore, a plasma-level controlled, dose-finding study for clozapine remains a crucial unmet need. Contrary to the assertion made in the critique by Prof Gøtzsche, there is robust evidence for a dose-response relationship in antipsychotic medications,[1-5] within but not outside [6] the licensed dose ranges for newer drugs. However, as clozapine is an old drug, proper dose-finding studies have never been conducted, which represents a significant gap in the literature.

We firmly believe in the Popperian philosophy of scientific inquiry, where hypotheses are continuously tested and refined through rigorous debate. In this context, we acknowledge the value of differing perspectives and appreciate the contributions of Prof. Gøtzsche.[7] However, we frequently observe that studies of lower methodological quality that support certain viewpoints are given disproportionate weight, whereas higher-quality studies that present conflicting findings are often dismissed. This discrepancy in interpretation, observed in the letter by Prof. Gøtzsche, creates a significant barrier to objective scientific discourse. The risk of misinformation is substantial when discussions are framed exclusively in terms of criticisms without a balanced presentation of supporting and opposing evidence. Evidence-based medicine necessitates a fair assessment of both supporting and contradictory data.

For instance, in the commentary, the limitation we acknowledged—our inability to access individual patient data (IPD) from some studies demonstrating clozapine's superiority—is dismissed with the assertion that data were withheld due to potential undisclosed biases. While data transparency is a valid concern, an alternative and more plausible explanation exists: many of these trials are over two decades old, and drug ownership has changed multiple times, as was the case in a study where the company made substantial efforts to provide the requested data.[8]

In the comment, the nationwide observational studies from Finland and Sweden, which consistently indicate clozapine's superior efficacy, are disregarded. These studies show that the highest mortality rates are among patients who do not receive antipsychotic treatment.[9] While we acknowledge that observational studies have inherent limitations, their findings cannot be dismissed outright. The effects observed may not be purely causal, as untreated individuals may receive less overall medical care. However, ignoring a priori large-scale, population-based

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studies is to our view not good scientific practice.

The burden of psychiatric disorders is profound. While systemic issues in psychiatry exist, dismissing the efficacy of antipsychotic medications entirely is not evidence-based and promotes an untenable nihilistic perspective. Psychotherapy monotherapy is not an effective treatment for psychosis, despite promising initial data in select populations.[10] Psychiatric professionals universally attempt to reason with patients experiencing hallucinations and delusions, yet such efforts prove ineffective. We support the expansion of Soteria-style wards, insufficient financial resources are a reason for psychiatry being too drug-centered. The effect sizes of antipsychotics have been often characterised variably, from “small” to “moderate” by researchers and clinicians. However, it is only those who need the medication that can infer about whether the efficiacy of the pharmacological interventions is worthwhile, given their side effects. A recent survey suggested that one in three people who show signs of depressions, find the small effect of antidepressants worth the side effects.[11] I (SL) was very sceptical about antidepressants due to their low effect sizes. However, I have suffered from generalized anxiety disorder since puberty. While psychotherapy was helpful, it never addressed the root of the problem. A few years ago, I started taking antidepressants, and they were a game changer for me—the anxiety simply vanished. After 30 years of suffering, this is certainly not a placebo effect.[12] We collaborate closely with patient organisations (https://www.bastagegenstigma.de/; https://psychose-seminar-muenchen.de/) some tell us that clozapine was the only drug that helped them.

Until similar studies are undertaken that will give a voice to the people with lived experience of psychosis, researchers and clinicians should refrain from making definitive statements about the clinical value of antipsychotics.

We strongly advocate for an evidence-based, balanced discussion regarding psychiatric treatment. Dismissing the efficacy of psychotropic medications without considering the totality of available evidence and views of the patients is neither scientifically rigorous nor beneficial to those who needs these treatments.

Sincerely,

Stefan Leucht, Johannes Schneider-Thoma, Konstantina Chalkou, Tasmin Hamza, Spyridon Siafis, Georgia Salanti

Competing interests: In the last three years SL has received honoraria for advising/consulting and/or for lectures and/or for educational material from Angelini, Apsen, Boehringer Ingelheim, Janssen, Karuna, Kynexis, Lundbeck, Medscape, Otsuka, Neurotorium, NovoNordisk, Orionpharma, Otsuka, Roche, Rovi, TEVA. The other authors declare no conflict of interest.

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Reviewer Closure

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The authors fail to address my substantial criticisms and talk about something else

Submitted 3/19/2025

Leucht et al. avoid addressing my criticisms and instead talk about something else. To my remark, with reference to a recent Cochrane review,[1] that “it won’t help increasing the dose, as adding drugs or increasing the dose do not result in better outcomes,” they claim that “there is robust evidence for a dose-response

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relationship in antipsychotic medications" and give five references.

None of their references are convincing. Three of them [2-4] are irrelevant because they do not address an increase in a better outcome but an increase in harms with increasing doses, which was not what I talked about.

The fourth reference is about relapse prevention,[5] which is also irrelevant because what people call relapse is most often also a harm, namely withdrawal effects after stopping with the drug.

That leaves one reference, which is a meta-analysis of 68 studies that I do not find convincing. The Cochrane review published only two years earlier had only included 10 studies, and the Cochrane authors were far more critical than Leucht et al. They noted that in most studies, the methods of randomisation, allocation and blinding were poorly reported, and the sample sizes were often small, limiting the overall quality of the evidence.

Moreover, I have issues with the statistical methods Leucht et al. used - models using regression splines, which represent a family of smooth functions that can describe a wide range of curves that consist of piecewise polynomials - and the confidence intervals were wide.

To suddenly talk of something else, as though it had a bearing on the matter, is a classic diversion, according to philosopher Arthur Schopenhauer's book, The art of always being right.[7] Leucht et al's focus on dose-response relationships have nothing to do with my main criticisms of their paper, which still stand.

Disclosures, Funding & Conflicts of Interest

None in relation to this paper.

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